Claims

1. A pharmaceutical formulation comprising a pharmaceutical acceptable salt of glycopyrronium, a solvates or physiologically functional derivative thereof in combination with an active pharmaceutical ingredient being a compound selected from the group consisting of roflumilast, pharmaceutically acceptable salts of roflumilast, solvates or physiologically functional derivative thereof and a pharmaceutically acceptable carrier and/or one or more excipients, and optionally one or more other therapeutic ingredients.

2. Formulation according to claim 1, wherein pharmaceutical acceptable salt of glycopyrronium and roflumilast are contained in the same pharmaceutical formulation (fixed combination).

3. Formulation according to claim 1, wherein pharmaceutical acceptable salt of glycopyrronium and roflumilast are contained in different pharmaceutical formulations (free combination).

4. Formulation according to claim 1, comprising a compound selected from the group of N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide, 3-cyclopropylmethoxy-4-difluoromethoxy-N-(3,5-dichloropyrid-4-yl 1-oxide)benzamide and salts or solvates thereof.

5. Formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is selected form the group of compounds racemic forms [S,S-, S,R, R,S- and R,R-forms] of the pharmaceutical acceptable salt of glycopyrronium in any mixing ratio and enantiomerically enriched S,S-, S,R, R,S- and R,R-forms of the pharmaceutical acceptable salt of glycopyrronium.

6. Formulation according to claim 5, wherein the enantiomerically enriched form of the pharmaceutical acceptable salt of glycopyrronium is the R,R-form (i.e. (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium).

7. Formulation according to claim 6, wherein the R,R-form has an enantiomeric purity of 90% minimum enantiomeric excess (ee), preferably 95 % ee, more preferably more than 98 % ee, and in particular preferably more than 99.5 % ee.

8. Formulation according to claim 1 wherein the pharmaceutical acceptable salt of glycopyrronium is (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide, which substantially does not contain glycopyrronium in the S,S-, S,R- and/or R,S- forms.

9. Formulation according to claim 1, comprising pharmaceutical acceptable salt of glycopyrronium and roflumilast in an amount and ratio to be effective for a twice or once daily treatment of a clinical condition in a mammal, such as a human, for which a PDE 4 inhibitor and/or an anticholinergic agent is indicated.

10. Formulation according to claim 1, which is suitable for administration by inhalation.

11. Formulation according to claim 1, which is suitable for nasal administration.

12. Formulation according to claim 1, wherein roflumilast is present in a form for oral administration and a pharmaceutical acceptable salt of glycopyrronium is present in a form suitable for administration by inhalation.

13. Pharmaceutical formulation according to claim 1, which is a dry powder and the carrier is a saccharide.

14. Pharmaceutical formulation according to claim 13, wherein the carrier is lactose monohydrate.

15. Method for the prophylaxis or treatment of a clinical condition in a mammal, such as a human, for which a PDE 4 inhibitor and/or an anticholinergic agent is indicated, which comprises administration of a therapeutically effective amount of a pharmaceutical formulation comprising roflumilast or a pharmaceutical acceptable salt, solvate, or physiologically functional derivative thereof in combination with a pharmaceutical acceptable salt of glycopyrronium, a solvate, or physiologically functional derivative thereof, and a pharmaceutical acceptable carrier and/or one or more excipients.

16. Method according to claim 15, wherein the clinical condition is selected from the group of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic and wheezy bronchitis, emphysema, respiratory tract infection and upper respiratory tract disease, rhinitis, allergic and seasonal rhinitis.

17. Method according to claim 16, which comprises a twice daily dosage regimen.

18. Method according to claim 16, which comprises a once daily dosage regimen.

19. Method according to claim 16, which comprises administration of a combination of the a pharmaceutical acceptable salt of glycopyrronium and roflumilast in the same administration form

by inhalation from an inhaler and wherein each actuation provides a dose therapeutically effective for a twice daily dosing regiment or for a once daily dosing regiment.

20. Dry powder inhalation product comprising a pharmaceutical composition according to claim 13.